Western Occupational and Environmental Medical Association
CME Webinar - October 20, 2011

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Opioid Use Guidelines for Chronic Pain Treatment

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PLEASE STAND BY - WEBINAR WILL BEGIN AT 12:00 PM PACIFIC TIME
For Audio: Call 866-740-1260 / Access Code: 764 4915#

Faculty Disclosure

Dr. Levy and Dr. Feinberg have both attested that they have nothing to disclose.

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Introduction

- Current climate
  - California Work Comp Institute data
  - State Compensation Insurance Fund
  - National News
- Describe what providers are not doing which can lead to problems
  - Discuss WOEMA opioid guidance document
- Implementing proper practices
- Frequently asked questions

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Experiences with Pain

- Affects 116 Million Americans
  - More than heart disease, diabetes and cancer combined
  - Indirect/direct medical expenses US $560-$630 Billion/year
  - #1 reason people out of work
- More than 300 million prescriptions for analgesics (125 million for Vicodin) are written each year for pain

Institute of Medicine – Relieving Pain In America 2011
http://www.iom.edu/Reports/2011/Relieving-Pain-in-America-A-Blueprint-for-Transforming-Prevention-Care-Education-Research.aspx

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Prescription Drug Abuse

- Youths
  - Fastest growing prescription abuse group
  - Obtain prescription opioids from family - friends
- Elderly
  - Includes pain patients who abuse opiate meds
  - Users typically have co-morbid medical and psychiatric conditions
- Baby Boomers
  - Used drugs in the 1960's & 1970's

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Sources of Prescription Opioid Abuse

- 70% of prescription abuse of opioids is obtained from a friend or relative and 18% are from a single HCP

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California Work Comp Institute

Table 2. Percent of California WC Schedule II Prescriptions & Payments & Avg # of Schedule II Opioid Prescriptions Per Claim (Top 10% of Schedule II Prescribing Physicians)

Physician Ranking Based on # of Schedule II Scripts Written*	Cumulative Percent of All Schedule II Opioid Prescriptions	Cumulative Percent of All Schedule II Opioid Morphine Equivalents	Cumulative Percent of All Schedule II Opioid Payments
Top 1.0%	33.1%	41.0%	42.4%
Top 2.0%	46.2%	53.6%	55.8%
Top 3.0%	54.9%	62.4%	64.7%
Top 4.0%	61.3%	69.0%	70.8%
Top 5.0%	66.0%	74.1%	76.3%
Top 6.0%	69.7%	77.9%	80.1%
Top 7.0%	72.7%	80.9%	83.1%
Top 8.0%	75.2%	83.3%	85.1%
Top 9.0%	77.3%	85.3%	86.8%
Top 10.0%	79.2%	86.8%	88.2%
All Other Physicians	20.8%	13.2%	11.8%
Total	100.0%	100.0%	100.0%

* Each percentile includes approximately 93 physicians, so the top 1% represents 93 physicians, the top 2% represents 186 physicians, the top 3% represents 279 physicians, etc.

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Table 3A. Claim-Level and Provider-Level Outcomes (Top 10 Percent of Opioid Prescribers Based on Total Number of Schedule II Opioid Prescriptions)

	Schedule II Opioid Claim-Level Outcomes			Schedule II Opioid Provider-Level Outcomes		
Physician Percentile Ranking	Avg # of Schedule II Opioid Prescriptions per Claim per MD	Avg Mgs of Morphine Equivalents per Claim per MD	Avg Schedule II Opioid Payments per Claim per MD	Total # of Schedule II Opioid Claims per MD	Total Mgs. of Morphine Equivalents per MD	Total Schedule II Opioid $ Paid per MD
1st	15.5	66,451	$7,343	53.5	3,553,351	$392,667
2nd	11	36,183	$4,193	29.6	1,071,496	$124,164
3rd	10.9	38,195	$4,137	20.1	766,374	$83,002
4th	9.1	32,480	$3,209	17.6	570,663	$56,382
5th	8.6	31,863	$3,730	13.7	436,487	$51,091
6th	11	38,452	$4,117	8.5	326,638	$34,973
7th	8.4	28,266	$3,050	8.9	252,873	$27,289
8th	7.8	25,006	$2,316	8.1	203,276	$18,828
9th	6.6	22,280	$1,980	8.2	183,270	$16,285
10th	7.4	20,207	$1,910	6.5	131,020	$12,384

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Table 3B. Claim-Level and Provider-Level Outcomes (All Schedule II Opioid Prescribers Based on Total Number of Prescriptions)

	Schedule II Opioid Claim-Level Outcomes			Schedule II Opioid Provider-Level Outcomes		
Physician Percentile Ranking	Avg # of Schedule II Opioid Prescriptions per Claim per MD	Avg Mgs. of Morphine Avg. Mgs. of Morphine Equivalents per Claim per MD	Avg Schedule II Opioid Payments per Claim per MD	Total # of Schedule II Opioid Claims per MD	Total Mgs. of Morphine Equivalents per MD	Total Schedule II Opioid $ Paid per MD
1st-10th	11.4*	42,905*	$4,677*	17.5	749,545	$81,706
11th-20th	5.5	13,879	$1,345	4.8	67,037	$6,494
21st-30th	3.6	7,764	$793	3	23,435	$2,394
31st-40th	2.3	4,303	$393	2.3	9,967	$910
41st-50th	1.8	2,698	$248	1.7	4,642	$427
51st-60th	1.4	1,922	$181	1.4	2,707	$255
61st-70th	1.1	1,369	$133	1.1	1,495	$145
71st-80th	1	1,217	$113	1	1,217	$113
81st-90th	1	1,022	$99	1	1,022	$99
91st-100th	1	1,232	$132	1	1,232	$132
Overall Average	7.2	24,831	$2,669	3.5	87,397	$9,393

* Revised May 9, 2011.

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State Compensation Insurance Fund (SCIF)

- Recently SCIF proposed several changes to their MPN
- Opioids prescribed for more than 60 days require pre-authorization

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Definition of Terms

- Addiction
  - A primary, chronic, neurobiological disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations
  - Behavioral characteristics include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, craving
- Pseudoaddiction
  - Syndrome of abnormal behavior resulting from undertreatment of pain that is misidentified by the clinician as inappropriate drug-seeking behavior
  - Behavior ceases when adequate pain relief is provided
  - Not a diagnosis; rather, a description of the clinical intention

Katz NP, et al. *Clin J Pain*. 2007;23:648-660

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Definition of Terms

- Tolerance:
  - Loss of a drug's effects over time or the need to increase the dose to maintain the effect
- Withdrawal:
  - A syndrome that occurs due to the cessation or reduction of prolonged use of a drug
  - Acute opioid withdrawal is characterized by dysphoria, nausea or vomiting, muscle aches, lacrimation, rhinorrhea, pupillary dilation, diarrhea, yawning, fever, or insomnia

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Federation of State Medical Boards

- Pain management is important and integral to the practice of medicine
- Use of opioids may be necessary for pain relief
- Use of opioids for other than a legitimate medical purpose poses a threat to the individual and society
- Physicians have a responsibility to minimize the potential for abuse and diversion
- Physicians may deviate from the recommended treatment steps based on good cause
- Not meant to constrain or dictate medical decision-making

❖ FSMB Model Policy for the Use of Controlled Substances for the Treatment of Pain @ http://www.fsmb.org/pdf/2004_grpol_Controlled_Substances.pdf

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Safely Managing Opioids in Chronic Pain

- Are opioids appropriate – for which patients
  - Assessment of the benefit and the risk of likelihood of abuse, misuse, or addiction
- Informed consent and agreement including
  - Goals of treatment (benefits)
  - Expectations (physician and patient)
  - Risks and alternatives
- Which opioids to use
- Monitoring the patient including UDT
- Expect and treat side-effects
- How long to treat

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Common Side-Effects

- Constipation
- Nausea
- Vomiting
- Somnolence
- Asthenia including fatigue
- Dizziness

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Opioid Agreement

- You will not obtain any other prescription for controlled medication from another source/physician
- Our staff may communicate with any pharmacy or health care professional regarding your medications
- Medication will only be refilled during regular office hours
- Lost narcotic medication cannot be replaced
- Stolen narcotic medication MAY be replaced provided you obtain a police report and are seen in the office

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Safely Managing Opioids in Chronic Pain

- Initiation and Titration of Chronic Opioid Therapy
  - Treatment individualized
  - Always a trial
- Monitoring patients on opioids
  - Level of function
  - Progress toward predetermined goals
  - Presence of adverse events
  - Compliance (or lack of)
- Co-Interventions
  - Psychological and behavioral approaches – CBT
  - Functional restoration physical rehabilitation

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Risk Factors for Abuse

- Personal or family history of substance abuse
- History of adverse childhood experiences (ACE)
  - Neglect
  - Physical, emotional, sexual abuse
- Mental illness
- Psychological stress (chemical coping)

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Primary Risk Factor for Misuse

- Uncontrolled or inadequately treated pain

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Identifying at Risk Patients

- Predictive tools
- Aberrant behaviors
- Urine drug testing
- Prescription monitoring programs
- Severity and duration of pain
- Pharmacist communication
- Family and friends
- Patients

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Signs of Potential Abuse and Diversion

- Request appointment toward end-of-office hours
- Arrive without appointment
- Telephone/arrive after office hours when staff are anxious to leave
- Reluctant to have thorough physical exam, diagnostic tests, or referrals
- Fail to keep appointments
- Unwilling to provide past medical records or names of HCPs
- Unusual stories
- *However, emergencies happen: not every person in a hurry is an abuser/diverter*

Drug Enforcement Administration. *Don't be Scammed by a Drug Abuser.* 1999. Cole BE. *Fam Pract Manage.* 2001;8:37-41.

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Risk Assessment Tools

- ORT: Opioid Risk Tool
- SOAPP: Screener and Opioid Assessment for Patients with Pain
- DIRE: Diagnosis, Intractability, Risk, Efficacy
- COMM: Current Opioid Misuse Measure
- PMQ: Pain Medication Questionnaire
- DAST-10: Drug Abuse Screening Test

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Risk Assessment Tools

- ORT, SOAPP & DIRE
  - Best assess abuse potential among those being considered for long-term opioid therapy
- COMM & PMQ
  - Characterize degree of medication misuse or aberrant behavior once opioids are started
- DAST-10 & PMQ
  - More suitable for assessing current alcohol and/or drug abuse than potential for such abuse

Passik SD, et al. *Pain Med.* 2008;10 Suppl 2:S145-166.

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Stratifying the Risk

Low Risk	Moderate Risk	High Risk
No past/current history of substance abuse	History of treated substance abuse	Active substance abuse
Noncontributory family history of substance abuse	Significant family history of substance abuse	Active addiction
No major or untreated psychological disorder	Past/comorbid psychological disorder	Major untreated psychological disorder
	Not actively addicted	Significant risk to self and practitioner

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Opioid Risk Tool Clinician Form

(includes point values to determine scoring total)

Mark each box that applies.

	Female	Male
1. Family History of Substance Abuse:		
Alcohol	☐ 1	☐ 3
Illegal Drugs	☐ 2	☐ 3
Prescription Drugs	☐ 4	☐ 4
2. Personal History of Substance Abuse:		
Alcohol	☐ 3	☐ 3
Illegal Drugs	☐ 4	☐ 4
Prescription Drugs	☐ 5	☐ 5
3. Age (mark box if between 16-45)	☐ 1	☐ 1
4. History of Preadolescent Sexual Abuse	☐ 3	☐ 0
5. Psychological Disease:		
Attention Deficit Disorder, Obsessive-Compulsive Disorder, Bipolar, Schizophrenia	☐ 2	☐ 2
Depression	☐ 1	☐ 1
Scoring Totals:	____	____

Total Score Risk Category:
Low Risk: 1-3
Moderate Risk: 4-7
High Risk: ≥8

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High Risk Patients

- Refer to Pain Specialist or addictionologist

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Opioid Policies

- Federal laws
- State laws
- Regulatory guidelines
- Policy statements

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Risk Evaluation and Mitigation Strategies (REMS)

- The Food and Drug Administration Amendments Act of 2007 gave FDA the authority to require a Risk Evaluation and Mitigation Strategy (REMS) from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks

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Federal Regulations

- Must have physician-patient relationship
- Must have a chart
- Documentation of each Rx
  - Document reason for early refills
  - Document reason for any change in dosage
- Document expectation of treatment's effect
- Documentation of diagnosis causing pain

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The Rules!

- Cannot Rx Schedule II or III for family members
- Can provide samples of unscheduled drugs for family, but MUST document in a medical record
- Cannot Rx for anyone in sexual relationship, EVER
- Cannot Rx opioids for yourself, EVER
- Cannot Rx opioids to anyone (including friends) if you have not documented their H& P and have a current chart on file

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The 4 A's

- Analgesia
- Activities of Daily Living
- Adverse Events
- Aberrant Drug-Taking Behaviors

Passik S, Weinreb HJ (1998)
Passik SD, Weinreb HJ. *Adv Ther*. 2000;17:70-83.
Passik SD, et al. *Clin Ther*. 2004;26:552-561.

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Strategy for Prescribing Opioids

- Careful assessment and formation of an appropriate differential diagnosis
- Psychological assessment including risk of addictive disorders
- Informed consent
- Treatment agreement
- Appropriate **trial** of opioid therapy +/- adjunctive medications
- Assessment and reassessment of pain and level of function
- Regularly assess the 4 A's of pain medicine (Analgesia, Activities, Adverse Effects and Aberrant Behavior)
- Steps to reduce risk
- Thorough documentation in the medical records

Adapted from Gourlay DL, Heit HA et al Pain Med. 2005; 6 107-12

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WOEMA Guidance Document

Clinical Issue	ACOEM Guidelines	American Pain Society Guidelines	Canadian Pain Guidelines	Colorado Guidelines
Screen all patients for opioid risks, using a questionnaire?	Yes, all patients; SOAPP is suggested	Yes. Questionnaire "likely" to help; suggest SOAPP, PADT, or COMM	Consider using questionnaire; suggest Opioid Risk Tool (ORT)	No recommendation
Initiate opioids only after treatment failure?	Yes	No. Start chronic opioids when benefits are likely to outweigh risks	Physician should document "comprehensive knowledge of the patient's pain condition"	Yes
Urine drug screen on all patients on chronic opioids?	Yes	Urine drug screens recommended "periodically" in patients at high risk for drug abuse. "Consider" urine drug screens in low risk patients	No recommendation for routine urine drug testing; physician should screen by history for aberrant behaviors	Yes
Urine drug screen only for high risk with acute pain?	Yes	Recommended	No recommendation for routine urine drug testing	Yes
Frequency of urine drug screen?	2 to 4 times a year, random	Could be as often as weekly in "very high risk" patients; no other recommendation for frequency	No recommendation for routine urine drug testing at all	At least annually
Pain agreements for ALL patients on chronic narcotics?	Yes	Recommend written informed consent when starting chronic opioids. Sample "Pain Agreement"	Consider in patients at high risk for abuse; norecommendation for routine use of pain agreements	Yes
Pain agreements for "high risk" patients?	Yes	No recommendation; sample "Pain Agreement" included in Appendix	No recommendation for routine use of pain agreements	Yes
Discontinue/wean opioids if no functional improvement	Yes	Yes	No recommendation	No recommendation
Increase dose of meds if additional functional improvement obtained?	Yes	Yes	Yes	No recommendation
Maximum morphine-equivalent dose before additional screening?	N/A	200 MEQ (morphine equianalgesic dose)	200 MEQ (morphine equianalgesic dose)	N/A
Consultation with pain specialist recommended?	Yes, PRN	Primary care physician should continue to manage. Consider consult, at clinician's judgment	No	Required
Attempt periodic wean of opioids if functional improvement?	Yes	No recommendation	No recommendation	No recommendation

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Urine Drug Testing

- Advantages
  - Can confirm that prescribed drug is taken and that other drugs are not
  - Makes a strong statement potentially useful in monitoring
- Disadvantages
  - Cannot confirm that the proper dose is taken
  - Can be misinterpreted
  - Can be stigmatizing
- When to Test?

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UDT

- Initial testing (lab or POC) done with class-specific immunoassay drug panels
  - Typically do not identify individual drugs within a class (rapid results, not quantitative, low specificity)
- Followed by a technique such as GC/MS
  - To identify or confirm the presence or absence of a specific drug and/or its metabolites

Heit HA, Gourlay D. *J Pain Sympt Manage.* 2004:27:260-267.

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UDT

- Opiate immunoassays detect morphine and codeine
  - Do not detect synthetic opioids such as Methadone or Fentanyl
  - Do not reliably detect semisynthetic opioids such as Oxycodone, Hydrocodone, buprenorphine, Hydromorphone
- GC/MS will identify these medications

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Conclusions

- Use of opioids may be appropriate
  - Pathology that fits the problem
  - Improved level of function and increased ADLs
  - Decreased pain
  - Manageable side effects
- Balanced multimodal care
  - Use of opioids as part of complete pain care
  - Anticipation and management of side effects
- Maintain standard of care
  - H&P, F/U, PRN referral, functional outcomes, documentation

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Frequently Asked Questions

- 1) If you're treating a patient with opioids and after 90 days they refuse to sign a pain agreement, how do you proceed?

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Frequently Asked Questions

- 2) If a patient claims they are taking a medication and a random drug test fails to demonstrate the substance, do you stop prescribing immediately?

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Frequently Asked Questions

- 3) If a person were to be diverting their medications but takes a few tablets on the way to the office appointment, would this show up in their urine screen?

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Frequently Asked Questions

- 4) Do you screen all patients prior to initiating opioids? If so, how do you do so?

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Frequently Asked Questions

- 5) Can you spot patients likely to be diverting/abusing based on appearance and behavior?

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Frequently Asked Questions

- 6) How do you measure functional improvement while following a patient on opioids?

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Frequently Asked Questions

- 7) If you have a patient who is not showing any functional improvement while on opioids and in fact is having worsening pain, how do you handle this?

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Frequently Asked Questions

- 8) Is there a role for medications like Actiq, Lyrica, Cymbalta for treating axial low back pain?

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Frequently Asked Questions

- 9) I have had significant difficulty at times getting an authorization for an evaluation by a chronic pain specialist. Would you have recommendations of what the essential documentation components are that would best justify why a consultation is medically necessary?

References

- Managing Chronic Pain with Opioids in Primary Care, 2nd Edition
  http://www.painedu.org/load_doc.asp?file=guide.pdf
- Chou R, Fanciullo GJ, Fine PG, et al. Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. *J Pain* 2009; 10(2):113–130.
  http://download.journals.elsevierhealth.com/pdfs/journals/1526-5900/PIIS1526590008008316.pdf
- Guideline For the Use of Chronic Opioid therapy in Chronic Non-Cancer Pain by The American Pain Society in Conjunction with The American Academy of Pain Medicine
  http://www.ampainsoc.org/library/pdf/Opioid_Final_Evidence_Report.pdf
- Responsible Opioid Prescribing: A Physician's Guide by Scott M. Fishman, MD, Federation of State Medical Boards, 2007
  http://www.fsmb.org/pain-overview.html
- Opioid Prescribing Toolkit by Nathanial Katz, MD, Oxford University Press, 2011
- Opioid Clinical Management Guide by CARES Alliance
  http://www.caresalliance.org/

Internet Resources

- ***General Pain Sites***
  - PainEDU – *http://www.PainEDU.org*
  - painACTION – *http://www.painaction.com*
  - American Pain Society – *http://www.ampainsoc.org*
- ***Laws or Legal Issues Regarding Opioid Treatment***
  - Federation of State Medical Boards – *http://www.fsmb.org*
  - Drug Enforcement Administration, Office of Diversion Control - *http://www.deadiversion.usdoj.gov*
  - The Legal Side of Pain – *http://www.legalsideofpain.com*
  - University of Wisconsin Pain & Policy Studies Group – *http://www.painpolicy.wisc.edu*
- ***Risk Assessment Tools***
  - PainEDU – *http://www.PainEDU.org*
- ***Resources for Chronic Pain Patients***
  - American Chronic Pain Association – *http://www.theacpa.org*

Questions?

- For any additional information feel free to contact us at
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